Complete Summary

GUIDELINE TITLE

Acute otitis media: management and surveillance in an era of pneumococcal resistance.

BIBLIOGRAPHIC SOURCE(S)

Dowell SF, Butler JC, Giebink GS, Jacobs MR, Jernigan D, Musher DM, Rakowsky A, Schwartz B. Acute otitis media: management and surveillance in an era of pneumococcal resistance--a report from the Drug-resistant Streptococcus pneumoniae Therapeutic Working Group. Pediatr Infect Dis J 1999 Jan;18(1):1-9. [33 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Acute otitis media (AOM)
- Infection with drug-resistant Streptococcus pneumoniae

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Otolaryngology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations for the management of acute otitis media and the surveillance of drug-resistant Streptococcus pneumoniae (DRSP).
- To provide a framework for appropriate clinical and public health responses to the development of DRSP

TARGET POPULATION

Patients of all age groups with acute otitis media

INTERVENTIONS AND PRACTICES CONSIDERED

- A variety of surveillance systems to monitor the emergence of DRSP, including population-based active surveillance; sentinel site surveys of specimens collected by networks of participating laboratories; state health department surveillance systems; occasional published local surveys; and local microbiology laboratory information.
- First line antimicrobial agent treatment of AOM with high dose oral amoxicillin for high-risk patients for DRSP and standard dose oral amoxicillin for very low risk patients for DRSP.
- Alternative antimicrobial agents for clinical treatment failures with amoxicillin, including oral amoxicillin-clavulanate, oral cefuroxime axetil, intramuscular ceftriaxone, and clindamycin
- Varying empiric treatment of acute otitis media by geographic region
- Diagnostic tympanocentesis with culture and susceptibility testing of isolates
- Culture of middle ear drainage (otorrhea)

MAJOR OUTCOMES CONSIDERED

- Prevalence of DRSP and geographic distribution
- Antimicrobial susceptibilities of S. pneumoniae
- Treatment failure rate due to DRSP
- Efficacy of antimicrobial treatment of AOM (i.e., clinical improvement in signs and symptoms such as ear pain, fever, and tympanic membrane findings of redness, bulging or otorrhea after therapy)
- Safety of antimicrobial treatment of AOM
- Middle ear fluid concentrations of amoxicillin

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Experts reviewed the published and unpublished literature, including Medline searches since 1966, and made a summary presentation to the group. Other evidence used included experience from the experts (including clinicians, academicians, and public health practitioners) present.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After group presentations and review of background materials, subgroup chairs prepared draft responses to the five questions, discussed the responses as a group and edited those responses until agreement was reached.

The recommendation development work was not carried out in accordance with strictly defined consensus procedures. Rather, CDC sought the individual input of consultants, which was then used to produce recommendations for clinicians.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Centers for Disease Control and Prevention (CDC) sought the individual input of consultants, which was then used to produce recommendations to clinicians. After group presentations and a review of background materials, subgroup chairs prepared draft responses to five main issues; discussed the responses as a group; and edited the responses until agreement was reached.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In response to the rapid dissemination of drug-resistant Streptococcus pneumoniae (DRSP) and the evidence that such dissemination may have a substantial impact on the management of otitis media, the DRSP therapeutic working group makes the following recommendations:

- Amoxicillin should be the first-line antibiotic for acute otitis media.
- In view of the increasing prevalence of DRSP, the safety of amoxicillin at higher than standard dosages, and evidence that higher dosages of amoxicillin can achieve effective middle ear fluid concentrations; the initial dose of amoxicillin should be increased from 40 to 45 mg/kg/day to 80 to 90 mg/kg/day.
- Patients at very low risk for infection with DRSP (e.g., patients older than 2 years with no antimicrobial exposure in the preceding 3 months and no day-care attendance) would be appropriate candidates for amoxicillin given in the standard dosage of 40 to 45 mg/kg/day.
- In cases of clinically defined treatment failure, consideration should be given to identification of the etiologic agent by tympanocentesis for susceptibility testing to guide alternate antibiotic therapy.
- For clinically defined treatment failures after 3 days of therapy, an alternative agent should be selected after considering the likelihood of infection with resistant strains and should be effective with against DRSP and beta-lactamase-producing pathogens. Three agents that best meet these criteria include oral amoxicillin-clavulanate, oral cefuroxime axetil, and intramuscular ceftriaxone. Many of the 13 other Food and Drug Administration-approved otitis media drugs lack good evidence for efficacy against DRSP.
- Currently available data on local patterns of pneumococcal resistance from microbiology laboratories, health departments, or published surveys are often poorly representative of the outpatient population with AOM. In general such data should rarely be used to guide treatment decisions for AOM.
- Recommendations to improve surveillance include establishing criteria for setting susceptibility breakpoints for clinically appropriate antimicrobials to ensure relevance for treating AOM, testing middle ear fluid or nasal swab isolates in addition to sterile site isolates and testing of drugs that are useful in treating AOM.

- Future electronic laboratory surveillance may be both comprehensive and timely. Such surveillance may eventually allow clinicians to incorporate local susceptibility information into clinical decision making.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each individual recommendation is not given in the guideline. The recommendations were based primarily on a summarized review of the literature and the opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Optimal treatment of acute otitis media and effective management of drug-resistant S. pneumoniae
- Appropriate modification to laboratory surveillance to improve the utility of the information for clinicians treating acute otitis media

Subgroups Most Likely to Benefit:

Factors to consider in assessing the risk for infection with a resistant strain include recent antimicrobial exposure, age and day care attendance.

POTENTIAL HARMS

Clavulanate-dosing of higher than approximately 10 mg/kg/day would be expected to lead to a greater incidence of diarrhea.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

1. Because of the rapid changes in resistance patterns and newly available treatments, recommendations for treating acute otitis media require regular updating.
2. No controlled trial directly comparing standard dose with higher dose amoxicillin is available, and the Food and Drug administration has not approved amoxicillin at higher dosages. However, in view of the long history of safety and efficacy of amoxicillin, the evidence of superior middle ear fluid concentrations with higher dosages and the absence of any significant dose-related toxicity, it seems reasonable to use amoxicillin at 80 to 90 mg/kg/day as first line therapy for patients at high risk for drug-resistant S. pneumoniae.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Dowell SF, Butler JC, Giebink GS, Jacobs MR, Jernigan D, Musher DM, Rakowsky A, Schwartz B. Acute otitis media: management and surveillance in an era of pneumococcal resistance--a report from the Drug-resistant Streptococcus pneumoniae Therapeutic Working Group. Pediatr Infect Dis J 1999 Jan;18(1):1-9. [33 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Drug-Resistant Streptococcus Pneumoniae Therapeutic Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The Drug-Resistant Streptococcus Pneumoniae Therapeutic Working Group was convened by the Centers for Disease Control and Prevention (CDC) to respond to changes in antimicrobial susceptibility and included among its members practicing pediatricians, family physicians and internists, academicians, and public health practitioners

Authors: Scott F. Dowell, MD, MPH; Jay C. Butler, MD; G. Scott Giebink, MD; Michael R. Jacobs, MD; Daniel Jernigan, MD; Daniel M. Musher, MD; Alexander Rakowsky, MD; Benjamin Schwartz, MD, and the Drug-Resistant Streptococcus Pneumoniae Therapeutic Working Group.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Daniel Burch is an employee/shareholder at SmithKline Beecham, PLC; Ron Dagan received grants in the last 5 years from Roche, Pasteur Mérieux Connaught, Zeneca, Merck Sharp and Dohme, Marion Merrell Dow, Biotechnology General, SmithKline Beecham, Schering-Plough, Glaxo Wellcome, Eli Lilly, Pfizer, Bayer, Wyeth-Lederle; Kathryn Edwards received research funding from Wyeth Lederle Vaccines in Pediatrics for studies of Streptococcus pneumoniae vaccines in infants. Bruce Gellin has owned shares in Glaxo Wellcome (initially Burroughs Wellcome) for 10 years. According to the 1998 Physician´s Desk Reference (PDR), Glaxo Wellcome makes the following antibiotics: Ceftin, Ceptaz, Fortaz, Septra and Zinacef. G. Scott Giebink is a SmithKline Beecham Grantee and a Neoso Pharmaceuticals Grantee. Michael Jacobs received honoraria and research grants from Bayer Pharmaceuticals, Centers for Disease Control and Prevention, Daiichi Pharmaceuticals, Eli Lilly and Co., Glaxo Pharmaceuticals, Hoechst Marrion Roussel Pharmaceuticals, Marion Merrell Dow Lepetit Pharmaceuticals, Meifi Pharmaceuticals, Pfizer, Inc., Pharmacia/Upjohn Co., Rhono Roulenc Rorer Pharmaceuticals, Roche Pharmaceuticals, R. W. Johnson Pharmaceuticals, SmithKline Beecham Pharmaceuticals, Warner-Lambert Pharmaceuticals and Wyeth Ayerst/Lederle Pharmaceuticals, Jamos Jorgensen received a grant from Roche Laboratories, CME courses. Sheldon Kaplan received a grant from Roche Pharmaceuticals for surveillance study and is a member of the Pediatrics Advisory Committee for Ceftriaxone at Roche Pharmaceuticals. Keith Klugman received research funding from Hoechst Marion Roussel, Biochemie, Chiron Vaccines, SA Vaccine Producers, SmithKline Beecham, Roche Pharmaceuticals, Bayer, Swiss Serum Institute, Schering Plough and Wyeth Lederle Vaccines. Michael Poole received honoraria and consulting from Glaxo Wellcome, SmithKline Beecham, Upjohn Pharmaceuticals, Ortho McNeil and Bristol-Meyers Squibb; Joseph Plouffe received honoraria for lectures and research grants from Pfizer, Ortho, Bayer, Merck Sharp and Dohme, Bristol-Meyers Squibb, Upjohn and Rhone Poulenc.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic Copies: Not available at this time.

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

NGC STATUS

This summary was completed by ECRI on March 20, 1999. The information was verified by the guideline developer on April 30, 1999.

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